EXECUTIVE SUMMARY

The Prescription Drug User Fee Act of 1992 (PDUFA), as amended, requires the Food and Drug Administration (FDA or the Agency) to report annually on the financial aspects of its implementation of the Act. Required under PDUFA, this report covers fiscal year (FY) 2013.

PDUFA, as amended, specifies that the following three legal conditions must be satisfied each year for FDA to collect and spend PDUFA user fees:

1. FDA's overall Salaries and Expenses Appropriation, excluding fees, must equal or exceed FDA's overall FY 1997 Salaries and Expenses Appropriation, excluding fees and adjusted for inflation.

2. The fee amounts FDA may collect must be provided in appropriation acts.

3. FDA must spend at least as much from appropriated funds for the review of human drug applications as it spent in FY 1997, adjusted for inflation.

This report explains how FDA met these three legal conditions in FY 2013. The statements and tables in the report provide data on prescription drug user fee collections, expenditures, and carryover balances, as well as comparative data from earlier periods.

In FY 2013, FDA collected $728.6 million in prescription drug user fees, spent $666.9 million in user fees for the human drug review process, and carried a cumulative balance of $240.2 million forward for future fiscal years.

PDUFA user fees and appropriations in FY 2013 supported 3,655 full-time equivalents (FTEs), including salary and operational expenses, to support the process for the review of human drug applications.

Challenges FDA faces in FY 2014 include implementing the new programs and initiatives for the human drug and biologic review process agreed to in PDUFA V. FDA will continue to spend user fees to enhance the review program and to improve communications to meet the performance goals associated with this program.